

APPLICANTS: Gen Jorgensen, et al.
U.S.S.N.: 09/728,327

merits of this rejection, Applicants have deleted the terms of concern to the Examiner. Accordingly, Applicants respectfully submit that the claims conform to the requirements of §112, second paragraph, and therefore, request that this rejection be withdrawn.

Rejection Under 35 U.S.C. §103

Claims 9-32 were rejected under 35 U.S.C. §103 as reciting subject matter that would have been obvious to one of ordinary skill in the art at the time the invention was made in view of U.S. Patent No. 5,639,658 (Drobish et al.). For the following reasons, Applicants traverse the present rejection and submit that the claimed invention is patentable over the prior art.

The Invention

Claim 9 is directed to a system for processing biological cells maintained in a sterile environment and includes a supply module constructed and arranged to provide selected amounts of process chemicals, a cell module including a cell sensor constructed and arranged to provide selected amounts of process chemicals, a processing module constructed and arranged to process the biological cells, a set of conduits for connecting the supply module, the cell module and the processing module in a sterile manner, several valves constructed and arranged to control transfer of the biological cells and the process chemicals between the modules and several sensors constructed and arranged to detect the biological cells and the process chemicals and a control module operatively connected to the valves. The sensors, the processing module and the control module are constructed and arranged to receive data from the cell sensors and control the transfer and processing of the biological cells based on the cell sensor data. The modules are constructed and arranged to prevent unwanted contamination of the cells during processing. Independent claim 30 recites similar patentable features.

The Drobish et al. Reference

As understood by Applicants, Drobish et al. is directed to a split-feed cell fermentation method and system for producing a compound of interest. The reference is understood to

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disclose a cell culture system consisting of a fermentor connected to two feed vessels. The fermentor contains cultured cells submerged in a liquid nutrient medium. The fermentor is also equipped to oxygenate the cells in solution. Also included with the system are probes for pH, dissolved oxygen, and temperature measurements, a pressure sensor as well as one or more ports for addition of nutrient and/or other solutions such as antifoam from the feed vessels.

ANALYSIS

To establish a *prima facie* case of obviousness, three criteria are required. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must have taught or suggested to one of ordinary skill in the art at the time the invention was made all the claim limitations at the time the invention was made. See M.P.E.P. 2143.

Accordingly, Applicant submits that the outstanding rejection under § 103 fails at least to meet the third requirement of *prima facie* obviousness, in that Drobish et al., when taken alone or in combination with other prior art/knowledge in the art, would not have taught or suggested to one of skill in the art at the time the invention was made of all the claim limitations. Specifically, Drobish et al. fails at least to teach or suggest several sensors constructed and arranged to detect biological cells. Although Drobish et al. may teach or suggest probes for pH, dissolved oxygen, temperature measurements, and pressure, these are not probes, as used in the parent invention which are "arranged and constructed to detect biological cells and process chemicals." As disclosed and claimed in the present application, sensors such as a mass sensor, or a volume sensor, for detecting an amount of biological cells and send this data to a control module (see specification, page 4, lines 26-29). For at least these reasons, independent claims 9 and 30 are patentable over the prior art and Applicants respectfully request withdrawal of the § 103 rejection.

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Since the remainder of the claims are dependent upon either one or the other of claims 9 and 30, they are patentable for the same reasons.

CONCLUSION

In view of the foregoing remarks, Applicants submit that the issues raised in the outstanding Office Action have all been addressed. Accordingly, Applicants respectfully request favorable reconsideration and early passage to issue of the present application. However, if the Examiner is of the opinion that the application is not in condition for allowance, Applicants respectfully request that the Examiner contact Applicants' representative at 212-692-6803, to resolve and new or outstanding issues.

It is believed that no fees are due in connection with filing this Response. In the event that it is determined that fees are due, however, the Commissioner is hereby authorized to charge the undersigned's Deposit Account No. 50-0311.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 692-6803. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

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CLAIMS

9. [An interactive] A system for processing biological cells maintained in a sterile environment, comprising:

a supply module constructed and arranged to provide selected amounts of process chemicals;

a cell module including a cell sensor constructed and arranged to measure an amount of said biological cells supplied for processing;

a processing module constructed and arranged to process said biological cells;

a set of conduits for connecting said supply module, said cell module and said processing module in a sterile manner;

several valves constructed and arranged to control transfer of said biological cells and said process chemicals between said modules;

several sensors constructed and arranged to detect said biological cells and said process chemicals; and

a control module operatively connected to said valves, said sensors and said processing module, said control module being constructed and arranged to receive data from said cell sensor and control said transfer and said processing of said biological cells based on said cell sensor data;

wherein said modules are constructed and arranged to prevent unwanted contamination of said cells during said processing.

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10. The [interactive] system of claim 9 wherein said cell sensor includes a weight sensor constructed and arranged to weigh said supplied amount of said biological cells.

11. The [interactive] system of claim 9 wherein said cell sensor includes a volume sensor constructed and arranged to measure volume of said supplied amount of said biological cells.

12. The [interactive] system of claim 9 wherein said control module is further arranged to calculate amounts of said process chemicals based on said cell sensor data.

13. The [interactive] system of claim 9 wherein said control module is further arranged to select an algorithm for said processing based on said cell sensor data.

14. The [interactive] system of claim 9 wherein said supply module includes several containers constructed and arranged to hold said process chemicals at least some of them being in a liquid state.

15. The [interactive] system of claim 9 wherein said process chemicals include an enzyme solution.

16. The [interactive] system of claim 9 wherein said process chemicals include a saline solution.

17. The [interactive] system of claim 9 wherein said processing module includes a processing vessel constructed and arranged to vary its volume relative to a volume of said process chemicals and said cells transferred to said vessel for processing.

18. The [interactive] system of claim 9 wherein said processing module includes a centrifuge.

19. The [interactive] system of claim 18 wherein said centrifuge is constructed and

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arranged to vary its volume by receiving a filling fluid arranged to occupy a selected volume.

20. The [interactive] system of claim 19 wherein said filling fluid is an expressor fluid designed to selectively express said process chemicals or said cells during centrifugation.

21. The [interactive] system of claim 9 wherein said processing module is constructed to agitate heat, cool or mix said processing chemicals and said cells.

22. The [interactive] system of claim 9 wherein said sensors include an optical sensor.

23. The [interactive] system of claim 9 wherein said sensors include a pressure sensor.

24. The [interactive] system of claim 9 wherein said sensors include a mass flow meter.

25. The [interactive] system of claim 9 wherein said sensors include a temperature sensor.

26. The [interactive] system of claim [26] 25 wherein said temperature sensor includes a [IR] infrared sensor constructed and arranged to measure a temperature of said cells and said process chemicals inside said processing module.

27. The [interactive] system of claim 9 further including a pump constructed and arranged to advance said material from said supply module to said processing module in said conduits.

28. The [interactive] system of claim 9 wherein said supply module further includes at least one supply sensor constructed and arranged to measure the amount of at least one of said process chemicals transferred to said processing module.

29. The [interactive] system of claim 28 wherein said supply sensor includes a mass sensor.

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30. A method of [controlling operation of] operating a cell processing system comprising a control module, a processing module connected in a sterile manner by a set of conduits to a cell module and to a supply module that provides selected process chemicals, and several sensors providing process data to said control module, said method including:

- providing in said cell module biological cells;
- measuring an amount of said cells supplied to said processing module for processing;
- providing in said supply module process chemicals according to a processing algorithm;
- dispensing from said supply module said process chemicals to said processing module based on said measure amount of said cells;
- processing said cells in said processing module; and
- storing said processed cell, whereby preventing unwanted contamination of said cells during said dispensing and said processing.